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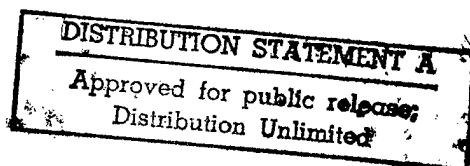
DOD ANIMAL RESEARCH

Improvements Needed in Quality of Biomedical Research Database



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United States
General Accounting Office
Washington, D.C. 20548

National Security and
International Affairs Division

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December 14, 1998

The Honorable Floyd Spence
Chairman
The Honorable Ike Skelton
Ranking Minority Member
Committee on National Security
House of Representatives

In 1992, congressional concerns were expressed about the lack of disclosure of the Department of Defense's (DOD) animal use programs and activities. In response, DOD began submitting annual reports to the Congress in 1994. In 1995, to respond to continued congressional concerns and direction, DOD established the Biomedical Research Database (BRD) containing information on individual research projects and training programs involving animals being conducted by its laboratories, military hospitals and bases, and contractors.

House Report 103-499, issued by the House Armed Services Committee in its consideration of the National Defense Authorization Act for Fiscal Year 1995, directed us to examine several issues related to DOD's administration of its animal research programs. We are examining the extent to which DOD's research using animals addresses validated military objectives, does not unnecessarily duplicate work done elsewhere, and incorporates methods to reduce, replace, and refine the use of animals. In the course of doing this work, we identified problems with the quality of information in the BRD. The purpose of this report is to bring these problems to your attention. We are continuing our work on the broader issues and will report the results of our review of DOD's use of animals in research at a later date.

Results in Brief

The BRD provides improved public access to information about DOD's use of animals in its research activities. However, we found instances in which the information in the BRD was inaccurate, incomplete, and inconsistent, resulting in inadequate public disclosure. Specifically, the fiscal year 1996 BRD (1) misstated the number of animal use projects because it omitted some projects that used animals and included others that did not involve animals; (2) did not include information, such as the numbers and types of animals used, that was identified in House Report 103-499; and (3) contained significant differences in the specificity reported for the research projects. Although we did not quantify the full extent of these

problems, the problems we have identified suggest a need for DOD action to improve the accuracy and extent of the information in the database.

Background

DOD provides information to the public about its animal use projects through two main sources—an annual report to the Congress and the BRD. The annual report to the Congress provides information in a summary form on animal use activities, including numbers and types of animals used, general purposes for which animals were used, and DOD's animal care and use oversight procedures. DOD provided its first annual report in 1994 in response to the direction of the House Armed Services Committee, as contained in its Committee Report on the National Defense Authorization Act for the Fiscal Year 1993.¹

In House Report 103-499, however, the House Armed Services Committee noted that DOD's annual report had not provided sufficient detail about its animal research programs and activities. The House Report directed DOD to "develop a mechanism for providing the Congress and interested constituents with timely information . . . about its animal use programs, projects, and activities, both intramural and extramural." One mechanism, according to the House Report, would be a database with information about the research goal and justification, cost, procedures, kinds and numbers of animals used, and information about the pain to which these animals are subjected.

In response to that report, in October 1995 DOD established the BRD, a database about individual projects using animals that is accessible by the public through the Internet. For each ongoing DOD animal use project, it provides a project summary that includes the funding amount, the location of the research, and a brief statement of the project's research objectives and methods. Research projects cover a broad range of topics such as using animals in the development of vaccines to protect against biological warfare agents and technologies to improve treatment methods for combat casualty care.

Information for the BRD is collected from DOD agencies and military commands, organizations, and activities involved in the performance and funding of animal care and use programs. Typically the researcher or the veterinary services department at each facility provides the information about each research project for the BRD and the annual report. This is information that facilities routinely maintain as part of the process of

¹H.R. Rept. No. 102-527.

granting researchers the approval to conduct research and then subsequently ordering animals for the research project. The BRD includes research funded by DOD as well as research performed by DOD that is funded by external sources such as the National Institutes of Health and the Alzheimer Association. The BRD, which is updated annually, contained 805 project summaries for fiscal year 1996. It was updated to reflect fiscal year 1997 projects on October 1, 1998, one year after the fiscal year ended; project summaries for fiscal year 1996 were replaced by those for fiscal year 1997.

DOD Has Created a Publicly Available Database on Its Animal Research Programs

DOD has made progress in making information available to the public on its animal research programs and activities. Prior to the creation of the BRD, information on animal research was contained as part of a larger Defense Technology Information Center (DTIC) database, which includes the broad range of DOD research and development projects. However, DOD did not require all of its animal research activities, such as those involving clinical training or investigations, to be reported to the DTIC database. DOD now requires all animal research projects to be reported separately in the BRD. In addition, the BRD is publicly available on the Internet, while the DTIC database has restricted public access.

Problems With DOD's Animal Use Information

The fiscal year 1996 BRD had a number of problems, including inaccurate and incomplete disclosure of information about DOD's animal use projects. These problems stem from DOD not collecting certain valuable information from animal use facilities and not reporting certain other information that it did collect. Other problems of inaccuracy or inconsistency in the database were due to flawed data reported to DOD by facilities.

The BRD is inaccurate with respect to the number of animal use projects. For example, in the course of performing our work, we found seven projects or research protocols that were not included in the database. These projects were performed at three different DOD organizations: the Armed Forces Radiobiology Research Institute, the Army's Landstuhl Regional Medical Center, and the Marine Corp's Camp Lejeune Field Medical Service School. The animals used included goats, sheep, rodents, and nonhuman primates. Alternatively, we identified 19 projects in the fiscal year 1996 BRD related to medical research for biological defense that did not involve the use of animals that year (although they did involve animals in other years). In addition, we identified one project that was

reported twice in the database—two different DOD organizations reported the same project.

Cost information provided in the BRD is not always accurate and consistent. For example, the fiscal year 1996 funding amount provided in the BRD for some projects covered a longer period than just fiscal year 1996. In other cases, the amounts of funding shown was inconsistent because the funding for some projects was listed as an abbreviated notation of a larger amount without providing adequate explanation. For example, in the case of the project erroneously reported twice, one project summary showed funding as “28,” while the other showed the amount as “28000.” These discrepancies make it difficult, if not impossible, to accurately determine from the BRD the cost of these animal research projects for the fiscal year. Additionally, the BRD does not disclose the funding source for the projects, making it impossible to determine which projects were funded by DOD and which by external sources.

Furthermore, the BRD does not contain certain information identified in House Report 103-499. For instance, it does not provide the numbers and species of animals used for DOD projects nor does it include information about the pain to which animals were subjected. Summary information is provided for numbers and types of animals used and pain categories² in DOD’s annual reports to the Congress, but these reports lack information on individual programs and activities.

Another type of information that was mentioned in the House report is generally absent in BRD project summaries. Few project summaries identify the military or nonmilitary justification of the project. Although some of the projects are directly tied to a military goal, such as developing more effective transfusion fluids for combat casualties, others are not tied to a military goal but are still being done under a specific congressional directive, such as DOD’s extensive breast cancer research program. Without this information the Congress and the public cannot identify projects by the type of requirement they support. DOD does not collect information on the justification of each project as part of its data collection for the BRD.

The version of the BRD available to the public also does not contain a data field that describes the broader animal use categories listed in DOD’s annual report to the Congress on animal care and use. Examples of these categories are research on infectious diseases, research relating to combat

²DOD uses a system developed by the U.S. Department of Agriculture to categorize the level of pain or distress to which animals are exposed and whether their pain or distress is alleviated during the research project, for example, through the use of anesthesia.

casualty care, and training for medical personnel. The absence of this information prevents the public from identifying how individual research projects link together into these broader research areas.

We also found variations in the levels of specificity reported on the projects in the BRD. Whereas most of the 805 project summaries represent an individual line of research, several summaries report broad groups of research projects. For example, the Uniformed Services University of Health Sciences placed 64 separate project summaries in the BRD reflecting detailed distinctions among its various clinical research activities, such as "Virulence Mechanisms of Salmonella Typhi." In contrast, Fitzsimons Army Medical Center reports only two clinical research project summaries that are described broadly as "Animal-Facilitated Clinical Medicine Studies in Support of Graduate Medical Education" and "Animal-Facilitated Clinical Surgical Studies in Support of Graduate Medical Education." These two summaries merged as many as 29 separate projects. DOD guidance to the animal use facilities on preparing project summaries allows facilities broad discretion in determining what constitutes a project.

We identified one classified project in the BRD that involved research on animals for the development of a weapon system. While we found no problem with the information reported in the BRD for this project, it appears inconsistent with DOD's fiscal year 1996 annual animal care and use report to the Congress, which stated that no animals had been used for offensive weapons testing during fiscal year 1996.

Recommendations

We recommend that the Secretary of Defense continue to take steps to improve the BRD. Specifically, the Secretary should improve the data collection and reporting procedures to ensure that the BRD contains accurate, detailed information about individual animal research projects, including information on the number and species of animals used in each project, the research goal and justification, and the pain categories for each project as identified in House Report 103-499. In addition, to improve public accountability, we recommend that the Secretary provide other information in the BRD, such as the appropriate animal use categories for each project, consistent with information reported in the DOD's annual reports to the Congress, and ensure that the information contained in the BRD be presented in a uniform manner for all projects.

Agency Comments

In written comments on a draft of this report (see app. I), DOD partially concurred with our first recommendation and concurred with our second recommendation. Specifically, DOD said it will provide additional training to on-site veterinarians who are responsible for submitting data, take steps to clarify funding information for individual project summaries, include animal use categories for each project summary, and require reporting of all projects that have any animal use. They stated that they will institute these changes prior to the fiscal year 1999 annual report. DOD, however, expressed a concern that our recommendation to provide further detail on the number and species of animals, the research goals and justifications, and pain categories for each project summary would require an extensive upgrade of the existing BRD software and hardware capacity, duplicate information that is already available in the DOD annual report on animal use activities, and would not improve animal welfare. DOD also contended that information in the BRD is uniformly presented. DOD also provided technical comments, which we incorporated where appropriate.

The changes that DOD proposes adopting will improve the quality of the BRD. But we believe that additional detail on each project summary is necessary to respond to the original direction of the House Armed Services Committee as well as to improve public accountability. Moreover, we feel that this detail can be provided in the BRD without a significant increase in resource expenditures. As pointed out in this report, the number and species of animals used and the pain category of the research are collected on a routine basis by DOD research and training facilities as a means of monitoring and tracking animal use activities. Furthermore, much of this information is already gathered for the DOD annual report although it is only reported in terms of aggregate animal use and not by individual projects. DOD also needs to ensure a more consistent level of reporting of animal use activities. Facilities conducting clinical research, for example, should submit summaries for the BRD at a project rather than program level. Incorporating these additional changes would further improve what is an important source of information on animal welfare to the public.

Scope and Methodology

In the course of our work examining issues related to DOD's oversight of its animal research programs, we are reviewing the BRD because it contains information on individual animal use projects. As we reviewed information contained in the BRD, conducted interviews with DOD officials, reviewed relevant congressional reports, and performed data analyses to address

the objectives for our study, we identified problems with information in the BRD.

The BRD is prepared annually by DOD based on a questionnaire that it sends to those of its laboratories and contractors who use animals for research or training purposes. We reviewed the BRD in two forms. First, we selectively reviewed a version that is publicly available on the Internet (at <http://ocean.dtic.mil/basis/matrix/www/biowww/sf>). Second, DOD supplied us with an electronic file that also identified the animal use category (for example, research on infectious diseases) on the 805 projects in the 1996 database. We reviewed all the projects in three animal use categories involving medical research—biological defense, combat casualty care, and ionizing radiation. These categories comprise approximately 22 percent of the 805 projects. We reviewed the summaries in these categories and compared the information contained in them with other sources, including DOD's annual report to the Congress on its animal care and use programs for 1996.

We interviewed officials from DOD's Office of the Director of Defense for Research and Engineering; the Armed Forces Radiobiology Research Institute; the Uniformed Services University of the Health Sciences; the Office for Naval Research; the Naval Medical Research Institute; and Walter Reed Army Institute of Research in the Washington, D.C., area. We also interviewed officials from the U.S. Army Medical Research and Materiel Command in Frederick, Maryland; the Air Force Research Laboratory and the U.S. Army Clinical Investigations Regulatory Office in San Antonio, Texas; and the Army's Landstuhl Regional Medical Center in Landstuhl, Germany. We reviewed DOD documents and reports relevant to animal care and use as well as related congressional reports.

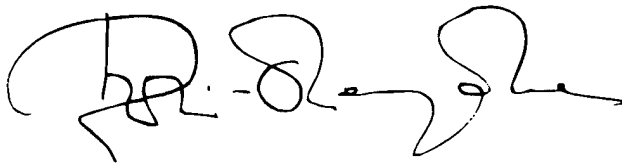
Our review was not based on a random sample of records from the BRD and, as a result, we have not drawn conclusions about the extent to which certain of our observations are present in the database as a whole.

We conducted our review from October 1997 to October 1998 in accordance with generally accepted government auditing standards.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from its issue date. At that time, we will send copies of this report to other interested congressional committees, the Secretary of Defense, and other

interested parties. We will also make copies available to others upon request.

Please contact us if you or your staff have questions concerning this report. Kwai-Cheung Chan can be reached at (202) 512-3652. Stephen Backhus can be reached at (202) 512-7101. Other major contributors are listed in appendix II.

A handwritten signature in black ink, appearing to read 'Kwai-Cheung Chan', with a stylized, flowing script.

Kwai-Cheung Chan, Director
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National Security and International Affairs Division

A handwritten signature in black ink, appearing to read 'Stephen P. Backhus', with a clear, legible script.

Stephen P. Backhus, Director
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Comments From the Department of Defense



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OCT 29 1998


Mr. Kwai-Cheung Chan
Director, Special Studies and Evaluation
National Security and International Affairs Division
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Chan:

This is the Department of Defense (DOD) response to the General Accounting Office (GAO) draft, "DOD ANIMAL RESEARCH: Biomedical Research Database Needs Improvement," dated October 6, 1998, (GAO Code 713013/OSD Case 1703).

The DOD will take steps to improve the Biomedical Research Database by implementing changes outlined in the attached DOD response to Recommendation 1 prior to the FY99 annual report to Congress. The DOD will improve public accountability by including the DOD animal use category code and description in the publicly accessible portion of the DOD/MATRIS Biomedical Research Database and institute other changes as outlined in the attached DOD response to Recommendation 2. This will be accomplished prior to the FY99 annual report to Congress.

Additional technical corrections were provided separately to the GAO staff. The DoD appreciates the opportunity to comment on the draft report.


Delores M. Etter
Deputy Under Secretary of Defense
(Science and technology)

Enclosures



Appendix I
Comments From the Department of Defense

Now on p. 5.

RECOMMENDATION 1: The GAO recommended that the Secretary of Defense take steps to improve the biomedical research database (BRD). The GAO specifically recommended the Secretary improve data collection and reporting procedures to ensure that the BRD contains accurate, detailed information about individual animal research projects, including information on the number and species of animals used in each project, the research goal and justification, and the pain categories for each project as identified in House Report 103-499. (pp. 8-9/Draft Report)

DOD RESPONSE: Partially concur. DOD has complied with congressional requests for timeliness and detail for the animal use reporting. The DoD does not have an existing capability to specifically report information on the number and species of animals used in each project, the research goal and justification, and pain categories for each project because projects can span several years. Further, the number of animal subjects will vary during the course of an experiment, and is dependent upon the experiment outcome. To implement such a system would require an extensive upgrade to the existing BRD software and hardware capacity. While not currently being able to report specific projects, the DOD is taking additional steps to improve the Biomedical Research Database (BRD) and reporting procedures. Steps to improve the database and reporting include the following:

1. **Training.** Information reported in the database is only as good as the data submitted, collected and collated. By December 1, 1998, the DOD will provide training to the essential cadre of Laboratory Animal Veterinarians responsible for data entry and maintenance of the BRD.

2. **Provide Additional Information.** For data collected for FY99, the animal use category will be added to the projects listed on the BRD.

3. **Improve the Accuracy of BRD.** DOD will improve the accuracy of the FY99 BRD by:

A. Requiring and insuring that funding information on the BRD is consistent (i.e. for the funding datafield, 28,000 will be used consistently instead of 28K).

B. For Grants/contracts that last more than one year, the funding amount will also contain the number of years the grant/contract will cover (i.e. the funding datafield will be altered to include years, for example: "150,000, FY96-FY99").

4. **Inclusion of Projects.** DOD will emphasize the requirement to include all projects in

Appendix I
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the BRD that have animal use in any phase of the project. The goal of DOD is 100% reporting for all projects that have animals used in any component of the project.

RECOMMENDATION 2: To improve public accountability, the GAO recommended that the Secretary provide information in the BRD, consistent with information reported in DOD's annual reports to Congress, such as the appropriate animal use categories for each project and ensure that the information contained in the BRD be presented uniformly for all projects. (p. 9/Draft Report)

DOD Response: The DOD concurs with the GAO recommendation to add/include the DOD animal use category code and description (e.g., M1-Military Dentistry, C1-Clinical Medicine, T1-Training, Education, and/or Instruction of Personnel, etc.) to the publicly accessible portion of the DOD/MATRIS Biomedical Research Database (BRD) beginning with the FY98 update to the database that will occur on or about 1 Oct 99.

Additional detail requested by GAO in the BRD would require additional resources to implement, would essentially duplicate animal use information that is already available in the DOD annual report and would not improve animal welfare.

Whereas, the DOD concurs with the general premise of the GAO recommendation that information contained in the BRD be "uniformly presented", the DOD contends that the information in the BRD is "uniformly presented" across all the data fields for all work unit summaries. It is important to note that each work unit summary in the BRD is just that, "summary information" pertaining to a research effort funded by a DOD program element. In order to link the BRD with the annual report for information consistency, the DOD is considering placing the BRD on the website as an accessible PDF document file.

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